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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,029	12/12/2003	Ehud Amir	1662/6040761	2457
26646	7590	06/13/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			SACKEY, EBENEZER O	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,029	<b>Applicant(s)</b> AMIR ET AL.	
	<b>Examiner</b> EBENEZER SACKY	<b>Art Unit</b> 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### **Status of Claims**

Claims 1-84 are pending.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 are, drawn to crystalline DMSO solvate of gatifloxacin, classified in class 544, subclass 363.
- II. Claims 16-22 are, drawn to crystalline DMSO solvate of gatifloxacin, classified in class 544, subclass 363.
- III. Claim 23 is, drawn to crystalline form of gatifloxacin, classified in class 544, subclass 363.
- IV. Claims 24-35 are, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.
- V. Claim 36 is, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.
- VI. Claims 37-42 are, drawn to crystalline form of gatifloxacin, classified in class 544, subclass 363.
- VII. Claims 43-48 are, drawn to crystalline form of gatifloxacin, classified in class 544, subclass 363.
- VIII. Claims 49-54 are, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.

- IX. Claims 55-56 are, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.
- X. Claims 57-58 are, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.
- XI. Claims 59-64 are, drawn to a crystalline form of gatifloxacin, classified in class 544, subclass 363.
- XII. Claims 65-67 are, drawn to a method for making crystalline forms of gatifloxacin (CX), classified in class 544, subclass 363.
- XIII. Claims 68-70 are, drawn to a method for making gatifloxacin form (CY), classified in class 544, subclass 363.
- XIV. Claims 71-72 are, drawn to a method for making crystalline forms of gatifloxacin (CZ), classified in class 544, subclass 363.
- XV. Claims 73-74 are, drawn to a method for making crystalline forms of gatifloxacin (W), classified in class 544, subclass 363.
- XVI. Claims 75-76 are, drawn to a method for making crystalline forms of gatifloxacin (Y), classified in class 544, subclass 363.
- XVII. Claim 77 is, drawn to a method for making a crystalline form of gatifloxacin (Z), classified in class 544, subclass 363.
- XVIII. Claim 78 is, drawn to a method for making crystalline form of gatifloxacin (CH), classified in class 544, subclass 363.
- XIX. Claim 79 is, drawn to a method for making crystalline forms of gatifloxacin (RH), classified in class 544, subclass 363.

- XX. Claim 80 is, drawn to a method for making crystalline forms of gatifloxacin (V), classified in class 544, subclass 363.
- XXI. Claim 81 is, drawn to a method for making a crystalline form of gatifloxacin (T2RP), classified in class 544, subclass 363.
- XXII. Claim 82 is, drawn to a method form making crystalline form of gatifloxacin (HXI), classified in class 544, subclass 363.
- XXIII. Claim 83 is, drawn to a method for making crystalline forms of gatifloxacin (HX2), classified in class 544, subclass 363.

It is noted that claim 84 is drawn to a pharmaceutical formulation containing the various forms of crystalline gatifloxacin (i.e., forms CW, CX, CY, CZ, W, X, Y, Z, CHI, CH2, RH, HXI and HX2). The said claim will be examined along with the elected group if commensurate in scope therewith.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI and XII-XXII are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as shown in U.S. Patent number 6,413,969.

Additionally, Groups XII-XXII are drawn to twelve distinct processes for preparing gatifloxacin as demonstrated by the various steps and reactants. Moreover, the various forms of gatifloxacin (various x-ray diffractions) are capable of supporting their

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own patent because a reference anticipating one member will not necessarily render obvious the other member. Therefore, for the reasons given above, the restrictions set forth is proper because it would constitute an undue burden on the Examiner to examine all the inventions in this application.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different distinct spectroscopic properties, restriction for examination purposes as indicated is proper.

A telephone call was made to John B. Starr Jr. on 06/09/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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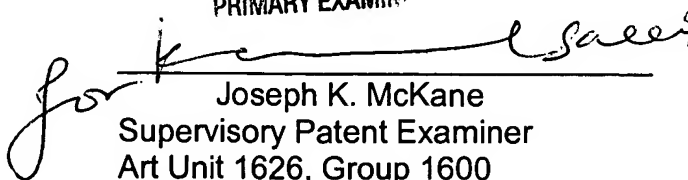
Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS  
June 10, 2006

KAMAL A. SAEED, Ph.D.  
PRIMARY EXAMINER



for \_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1600  
Technology Center 1